

REMARKS

The above-identified Application has been carefully reviewed with the Office Action of July 7, 2007, the Examiner's comments, and the art references cited therein in mind. In response thereto, Applicant submits the following arguments in support of patentability. Favorable reconsideration is hereby respectfully requested.

Initially, it is noted that the Applicants' arguments in the Response filed June 24, 2009 with respect to the rejection of claims 1 and 3-20 under 35 U.S.C. §103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. Now, upon further consideration, a new ground of rejection is made in view of Diebold/Anspach, Jr., this being the seventh Office Action in the present application.

Claims 1 and 3-20 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Diebold (EPO 856,293, submitted by the Applicants) in view of Anspach, Jr. (U.S. Patent No. 5,102,421). The Office Action opines that with respect to claims 1, 13 and 15, Diebold discloses an osteosynthesis and compression screw for coaptation of small bone fragments, the screw being formed by a single longitudinal body having a longitudinal axis, and comprising a proximal portion formed by a screw head provided with an outside head, an intermediate portion having no thread, and a distal portion provided with outside threads as best seen in Fig. 1. The Office Action contends that the screw head in the distal portion includes at least one groove (11) extending over the entire axial length of the threads, and secondly being formed through each thread in such a manner to form tapping means. It is then admitted that Diebold did not teach of at least one helical groove as claimed by the Applicants.

The Office Action then contends that in a similar art, Anspach, Jr. provides the evidence of the use of a screw with at least one helical groove (20, 22, 24, and 26, respectively), to facilitate the rotation of the screw into bone and to prevent the screw from coming out and concludes that given the teaching of Anspach, Jr., it would have been obvious to one of

ordinary skill in the art at the time the invention was made to modify the device from Diebold, as taught by Anspach, Jr., to facilitate the rotation of the screw into bone and to prevent the screw from coming out.

The dependent claims are then summarily rejected as a group, the Office Action stating that the above combination of references teaches all the limitations such as, the angle being 30°, the groove being constant, the variation in each groove, increases of the grooves towards the terminal zone of the screw, the tooth extending substantially axially, the central longitudinal bore, as set forth in Col. 4, lines 29-58 and Col. 5, lines 1-31; and as best seen in Figs. 1-6 of Diebold; also as set forth in Col. 3, lines 6-25 and as best seen in Figs. 1-5 of Anspach, Jr.

This rationale is both incomplete and improper in view of the established standards for rejections under 35 U.S.C. § 103.

In this regard, the MPEP section 2141 states:

The Supreme Court in KSR reaffirmed the familiar framework for determining obviousness as set forth in *Graham v. John Deere Co.* (383 U.S. 1, 148 USPQ 459 (1966))... As reiterated by the Supreme Court in KSR, the framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:

- (A) Determining the scope and content of the prior art; and
- (B) Ascertaining the differences between the claimed invention and the prior art; and
- (C) Resolving the level of ordinary skill in the pertinent art.

In addition:

When applying 35 U.S.C. 103, the following tenets of patent law must be adhered to:

- (A) The claimed invention must be considered as a whole;
- (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;
- (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention and
- (D) Reasonable expectation of success is the standard with which obviousness is determined.

Hodosh v. Block Drug Co., Inc., 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986).

As reflected above, the foregoing approach to obviousness determinations was recently confirmed by the United States Supreme Court decision in *KSR INTERNATIONAL CO. V. TELEFLEX INC. ET AL.* 550 U.S. 1, 82 USPQ2d 1385, 1395-97 (2007), where the Court stated:

In *Graham v. John Deere Co. of Kansas City*, 383 U. S. 1 (1966), the Court set out a framework for applying the statutory language of §103, language itself based on the logic of the earlier decision in *Hotchkiss v. Greenwood*, 11 How. 248 (1851), and its progeny. See 383 U. S., at 15–17. The analysis is objective:

“Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.” *Id.*, at 17–18.

The Court quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that “[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” (MPEP 2141). Simply stated, the Office Action has failed to at least (1) ascertain the differences between and prior art and the claims in issue; and (2) resolve the level of ordinary skill in the art. Furthermore, the alleged rationale for combining the references is merely an improper conclusory statement that embodies clear and improper hindsight rationale.

This rejection is respectfully traversed. For at least the reasons set forth below, it is clear that the Office’s approach for assessing patentability is once again an *ex post facto* approach, but which is furthermore and primarily based on an incorrect assessment of the teaching of Anspach, Jr.

The Diebold reference is well known to the Applicants, since the Applicants have an exclusive license for this particular patent. Diebold discloses three different embodiments, illustrated respectively by (1) Figs. 1-5, (2) Figs. 3A-5A, and (3) Fig. 6. The first embodiment of Figs. 1-5 has grooves but they are not helical, as acknowledged by the Office. The grooves of the first embodiment are classical straight grooves.

As to Anspach, Jr., the statements in the Office Action illustrate conclusively that the Office has apparently missed some important technical points which are clearly taught in the reference. Contrary to the Office Action, Anspach, Jr. does not disclose a screw, the element referred to by the Office as being a screw is instead an anchor or rivet (Col. 1, lines 31, 32, 42, and 64 or Col. 2, lines 4, 7, 9, etc.). An anchor or rivet has nothing in common with a screw. A screw has spiral threads and needs to be turned to be driven into a surface, the rotation of the screw being changed into a translational motion of the screw due to the threads. An anchor or rivet has no thread and needs to be impacted to be driven into a surface, just like a nail. This is well known to those skilled in the art and is explained in detail in the Anspach, Jr. reference (see, for example, Col. 2, lines 3-9).

Actually, the spiral grooves disclosed by Anspach, Jr. are intended to cause the anchor or rivet to rotate as it is driven into place (Col. 2, lines 19-23). Therefore, the technical purpose of the spiral grooves 20, 22, 24, and 26 of Anspach, Jr. is not to "facilitate" rotation of the anchor or rivet (which would imply that there will be a rotation without the spiral grooves which is not technically correct; without the grooves, a rivet or anchor does not rotate as it is impacted), but to impart a rotational motion to the anchor or rivet as it is impacted, by forming a plurality of serrations 30, 32, 34, and 36 (see Col. 3, lines 12-13 and 19-21). The purpose of the spiral grooves is thus to convert the forward motion of the anchor or rivet as it is impacted into a rotational motion. The spiral grooves of Anspach, Jr. additionally form serrations to prevent the suture anchor from being withdrawn. (Col. 3, lines 22-26). In other words, the rivet

of Anspach, Jr. and the claimed screw are totally different devices that operate in an opposite way.

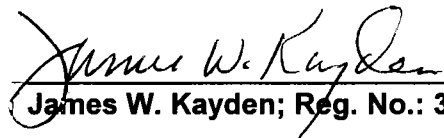
As in the previous three rejections, the Office has proffered non-analogous art. It is not sufficient in such a complex and detailed area of the medical device arts, to put forth a reference simply because it pertains to any medical field. Analogous art would at least be from the field of bone-fixing screws. It is submitted that one of ordinary skill in this art would hardly look for suture-securing rivets to solve the technical problem solved by the Applicants.

For at least the above reasons, it is clear that (a) Anspach, Jr. is not in the field of Applicants' endeavor, since it relates to an anchor or rivet for attaching sutures to bone and not to a screw for coaptation of small bone fragments; and (b) Anspach, Jr. is not reasonably pertinent to the particular problem with which the Applicants were concerned. The real and objective teaching of Anspach, Jr. is providing a rivet (which has no thread and has to be impacted) with spiral grooves that caused the rivet to rotate as it is impacted. This teaching is of absolutely no interest to a screw designer, since a screw is specifically designed to rotate and should not be impacted (as it would break the threads). Providing a screw with grooves does not facilitate rotation and does not prevent the screw from coming out; actually, it is the threads of the screw that facilitate rotation and prevent the screw from coming out. The objective problem with which the Applicant was concerned was to provide a compression screw for small bone fragments that is very aggressive but also resistant. Anspach, Jr. is not concerned by aggressiveness or resistance issues; actually, the rivet is provided with spiral grooves only for causing the rivet to rotate upon impaction. Anspach, Jr. contains absolutely no indication as to the potential effect of a spiral shaped groove concerning the resistance of a screw.

CONCLUSION

With the amendments presented herein, it is believed that all the claims remaining in the Application are in condition for allowance. Early and favorable action in this regarding is hereby respectfully requested. Should there be any minor informalities remaining, the Examiner is respectfully requested to call the undersigned attorney so that this case may be passed to issue at an early date.

Respectfully submitted,


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